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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/620,287

07/15/2003

Patrick J. Sweeney

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EXAMINER

KOHARSKI, CHRISTOPHER

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

07/27/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/620,287

Applicant(s)

SWEENEY, PATRICK J.

Examiner

Christopher D. Koharski

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed on 5/17/2007 in which no claims were amended, currently claims 1-17 are pending for examination in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 4-9 and 13-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Sasso et al. (2004/0225292). Sasso et al. discloses a bone anchor and methods of using the same.

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Regarding claims 1-2, 4-9 and 13-17, Sasso et al. discloses a device (10) for delivering a substance to a bone comprising a bone screw (12) comprising two ends (12a, 22) connected by a shaft wherein the shaft (30) is cannulated along a portion of its length, one or more bone-screw fenestrations disposed along its length (32), an insert (14) which is permeable to a fluid disposed inside the bone-screw wherein the insert is cannulated and has one or more fenestrations (54) to provide a delivery pathway for substance through the bone-screw (Figures 1-12). Additionally, the insert partially blocks one of the fenestrations (Figures 2-3) and the cannulation of the shaft runs the entire length of the bone screw, the screw is self tapping ([0023]) and the screw/insert is composed of various alloys ([0033]), and the screw is capable of being used for fixation (Figure 12). Sasso et al. further discloses a substance reservoir (5) attached to the end of the bone screw (Figure 5).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 3 are rejected under 35 U.S.C 103(a) as being unpatentable over Sasso et al. in view of Nelson (5,702,372). Sasso et al. meets the claim limitations as described above except for the insert completely blocking a fenestration.

However, Nelson teaches a lined infusion catheter.

Regarding claim 3, Nelson teaches a body inserted conduit that contains an insert (20, 66) that completely blocks fenestrations (46) in an infusion device (Figures 1 and 3).

At the time of the invention, it would have been obvious to add the insert of Nelson to the device of Sasso et al. because the addition of the insert allows for control of flow through the device (see abstract, summary of invention). The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Nelson.

Claim Rejections - 35 USC § 103

Claim 10 is rejected under 35 U.S.C 103(a) as being unpatentable over Sasso et al. in view of Miller et al. (6,228,088). Sasso et al. meets the claim limitations as described above except for a substance reservoir that is attached to the one end of the bone screw and implanted subcutaneously.

However, Miller et al. teaches a combination drill bit and intramedullary catheter.

Regarding claim 10, Miller et al. teaches a bone screw (38) that has a reservoir that can be filled with a therapeutic agent (Figure 1) and is can be implanted under the skin (Figure 3).

At the time of the invention, it would have been obvious to add the internal reservoir of Miller et al. to the system of Sasso et al. because the addition of the implantable reservoir would allow for long-term outpatient treatment. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Miller et al.

Claim Rejections - 35 USC § 103

Claims 11-12 are rejected under 35 U.S.C 103(a) as being unpatentable over Sasso et al. in view of Wigness et al. (5,203,770). Sasso et al. meets the claim limitations as described above except for an implanted pump attached to the end of the bone screw.

However, Wigness et al. teaches a method and apparatus for catheterization.

Regarding claims 11-12, Wigness et al. teaches a bone screw (40) that has a pump (85) attached to the end of the screw for delivery of therapeutic agents (Figures 1-2 and 4-5).

At the time of the invention, it would have been obvious to add the internal pump of Wigness et al. to the system of Sasso et al. because the addition of a internal pump allows for long term controlled delivery of the therapeutic agent to the body. The references are analogous in the art and with the instant invention; therefore, a

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combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Wigness et al.

Response to Arguments

Applicant's arguments filed 5/17/2007 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Sasso et al. (2004/0225292) does not disclose an insert that is cannulated with one or more fenestrations and permeable to substance to be delivered to the bone.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts Sasso et al. discloses an insert (14) that is cannulated (52) (*def: a small tube for insertion into a body cavity or into a duct or vessel [Websters]*) and has one or more fenestrations (54) (*def: an opening in a surface (as a wall or membrane) [Websters]*), that makes the insert (14) permeable (*having pores or openings that permit liquids or gases to pass through [Websters]*) to a drug compound being supplied to the bone.

Additionally, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., "a permeable portion") are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 7:30am to 4:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 7/23/2002


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